

#19



+

PTO/SB/08B (10-01)  
Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		<b>Compleat if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	09/473,830
		Filing Date	December 28, 1999
		First Named Inventor	Leiden et al.
		Group Art Unit	1632/1633
		Examiner Name	Chen, Shin-Lin
		Attorney Docket Number	104914-127
Sheet	1	of	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
SL	A	Connolly, Daniel T et al., "Vascular Permeability Factor: A Unique Regulator of Blood Vessel Function," J. Cell. Biochem. 47:219-223 (1991)	
✓	B	Conrad, C.K. et al., "Safety of Single-Dose Administration of an Adeno-Associated Virus (AAV)-CFTR Vector in the Primate Lung," Gene Ther. 3:658-668 (1996)	
✓	C	Crumley, Gregg et al., "The Gene for Human Acidic Fibroblast Growth Factor Encodes Two Upstream Exons Alternatively Spliced to the First Coding Exon," Biochem. Biophys. Res. Commun. 171:7-13 (1990)	
✓	D	During, M.J. et al. "In Vivo Expression of Therapeutic Human Genes for Dopamine Production in the Caudates of MPTP-Treated Monkeys using an AAV vector," Gene Ther. 5:820-827 (1998)	
✓	E	Flotte, Terence R. et al., "Stable In Vivo Expression of the Cystic Fibrosis Transmembrane Conductance Regulator with an Adeno-Associated Virus Vector," Proc. Natl. Acad. Sci. USA 90:10613-10617 (1993)	
✓	F	Flotte, Terence et al., "A Phase I Study of an Adeno-Associated Virus-CFTR Gene Vector in Adult CF Patients with Mild Lung Disease," Hum. Gene Ther. 7:1145-1159 (1996)	
✓	G	Folkman, Judah et al., "Angiogenic Factors," Science 235:442-447 (1987)	
	H	Kotin, Robert M., "Prospects for the Use of Adeno-Associated Virus as a Vector for Human Gene Therapy," Hum. Gene Ther. 5:793-801 (1994)	
	I	Kourtis, A.P. et al., "Cardiac Gene Therapy with Adeno-Associated Virus as a Means of Achieving Graft-Specific Immunosuppression," Modern Pathology 8:Abstract No. 178 (1995)	
✓	J	Kurachi, Kotoku et al., "Sequence of the cDNA and Gene for Angiogenin, a Human Angiogenesis Factor," Biochemistry 24:5494-5499 (1985)	
SL	K	Kurokawa, Tsutomu et al., "Cloning and Expression of cDNA Encoding Human Basic Fibroblast Growth Factor," FEBS Lett. 213:189-194 (1987)	

RECEIVED

JUL 16 2002

TECH CENTER 1600/2900

Examiner Signature	Shin-Lin Chen	Date Considered	4-3-03
--------------------	---------------	-----------------	--------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of

**Complete if Known**

Application Number	09/473,830
Filing Date	December 28, 1999
First Named Inventor	Leiden et al.
Group Art Unit	1632/1633
Examiner Name	Chen, Shin-Lin
Attorney Docket Number	104914-127

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
SM	L	Lebkowski, Jane S. et al., "Adeno-Associated Virus: a Vector System for Efficient Introduction and Integration of DNA into a Variety of Mammalian Cell Types," Mol. Cell. Biol. 8:3988-3996 (1988)	
	K	Leung, David W. et al., "Vascular Endothelial Growth Factor is a Secreted Angiogenic Mitogen," Science 246:1306-1309 (1989)	
	M	Lynch, Carmel M. et al., "Adeno-Associated Virus Vectors for Vascular Gene Delivery," Circ. Res. 80:497-505 (1997)	
	N	Maeda, Yoshikazu et al., "Gene Transfer into Vascular Cells Using Adeno-Associated Virus (AAV) Vectors," Cardio. Res. 35:514-521 (1997)	
	O	Monahan, P.E. et al., "Direct Intramuscular Injection with Recombinant AAV Vectors Results in Sustained Expression in a Dog Model of Hemophilia," Gene Ther. 5:40-49 (1998)	
	P	Podsakoff, Greg et al., "Efficient Gene Transfer into Nondividing Cells by Adeno-Associated Virus-Based Vectors," J. Virol. 68:5656-5666 (1994)	
	Q	Schaper, W., "Angiogenesis in the Adult Heart," Basic Res. Cardiol. 86(Supp. 2):51-56 (1991)	
	R	Snyder, Richard O., "Persistent and Therapeutic Concentrations of Human Factor IX in Mice After Hepatic Gene Transfer of Recombinant AAV Vectors," Nature Genet. 16:270-276 (1997)	
	S	Svensson, Eric C. et al., "Efficient and Stable Transduction of Cardiomyocytes After Intramyocardial Injection or Intracoronary Perfusion With Recombinant Adeno-Associated Virus Vectors," Circulation 99:201-205 (1999)	
SM	T	"Phase I Randomized Study of Adeno-Associated Virus-CFTR Vector in Patients with Cystic Fibrosis," <a href="http://www.clinicaltrials.gov/ct/gui/c/w1r/show/NCT00004533?order=1&amp;JservSessionIdzone_ct=xnrwsoycu1">www.clinicaltrials.gov/ct/gui/c/w1r/show/NCT00004533?order=1&amp;JservSessionIdzone_ct=xnrwsoycu1</a> (downloaded from website on June 13, 2002)	

RECEIVED

JUL 16 2002

TELETYPE CENTER 1600/290

Examiner  
Signature

Shin-Lin Chen

Date

Considered

4-3-03

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PTO/SB/08A (08-00)  
Approved for Release through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE  
a collection of information unless it contains a valid OMB control number.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**Complete if Known**

<b>Application Number</b>	09/473,830
<b>Filing Date</b>	December 28, 1999
<b>First Named Inventor</b>	Leiden
<b>Group Art Unit</b>	1632
<b>Examiner Name</b>	Shin Lin Chien
<b>Attorney Docket Number</b>	104914.127US1

*(use as many sheets as necessary)*

Sheet 1 of 1

[illegible][illegible]

4-303

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**